

required under 35 U.S.C. 121:

- I. Claims 1-10 and 15-16, drawn to a transgenic non-human mammal expressing a transgene encoding acid.alpha-glucosidase into the milk of the mammal and use of the animal to product acid.alpha-glucosidase by recovering the milk and the milk, classified in class 800;800, subclass 14.7.
- II. Claim 11, drawn to a method of incorporating milk comprising acid.alpha-glucosidase into a food product, classified in class 424, subclass 439.
- III. Claims 12-14, drawn to method of purifying acid.alpha-glucosidase from milk and the purified product, classified in class 530;530, subclass 412;350.
- IV. Claims 18-53 and 62-67, drawn to a pharmaceutical comprising acid.alpha-glucosidase and a method of treating disease using acid.alpha-glucosidase, classified in class 530;514;424, subclass 350;2;94.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct because the transgenic mammal can be used to product a source of acid.alpha-glucosidase protein for purification while the methods of Invention II can be used to make a food product. The protocols and reagents required for the transgenic mammal and the methods of making a food product are materially distinct and separate. The mammal does not require the methods and the methods do not require the mammal. Furthermore, the inventions are classified differently and the burden required to search Inventions I and II together would be undue.

Inventions I and III are patentably distinct because the transgenic mammal can be used to produce a source of milk comprising acid.alpha-glucosidase while the methods of Invention III can be used to purify acid.alpha-glucosidase from milk. The protocols and reagents required for the transgenic mammal and the methods purifying are materially distinct and separate. The mammal does not require the methods and the methods do not require the mammal. Furthermore, the inventions are classified differently and the burden required to search Inventions I and III together would be undue.

Inventions I and IV are patentably distinct because the transgenic mammal can be used to produce a source of milk comprising acid.alpha-glucosidase while the

pharmaceutical and methods of Invention IV can be used to treat disease. The protocols and reagents required for the transgenic mammal and the pharmaceutical are materially distinct and separate. The mammal does not require the pharmaceutical and the methods do not require the mammal. Furthermore, the inventions are classified differently and the burden required to search Inventions I and IV together would be undue.

Inventions II and III are patentably distinct because the methods of Invention II can be used to generate a food product comprising acid.alpha-glucosidase while the methods of Invention III can be used to purify acid.alpha-glucosidase from milk. The protocols and reagents required for the food product and the methods purifying are materially distinct and separate. The food product does not require the methods and the methods do not require the food product. Furthermore, the inventions are classified differently and the burden required to search Inventions II and III together would be undue.

Inventions II and IV are patentably distinct because methods of Invention II can be used to generate a food product comprising acid.alpha-glucosidase while the pharmaceutical of Invention IV can be used to treat disease intravenously. The protocols and reagents required for the methods and the pharmaceuticals are materially distinct and separate. The methods do not require the pharmaceutical and pharmaceuticals do not require the methods of Invention II. Furthermore, the inventions are classified differently and the burden required to search Inventions II and IV together would be undue.

Inventions III and IV are patentably distinct because methods of Invention III can be used purify acid.alpha-glucosidase from milk while the pharmaceutical of Invention IV can be used to treat disease intravenously. The protocols and reagents required for the methods of purifying and the pharmaceutical are materially distinct and separate. The methods of purifying do not require the pharmaceuticals and the pharmaceuticals do not require the methods. Furthermore, the inventions are classified differently and the burden required to search Inventions III and IV together would be undue.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification,

restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### **ELECTION**

Applicants provisionally elect Group I, claims 1-10 and 15-16, drawn to a transgenic non-human mammal expressing a transgene encoding acid.alpha-glucosidase into the milk of the mammal and use of the animal to product acid.alpha-glucosidase by recovering the milk and the milk, with traverse.

#### **TRAVERSAL**

Applicants respectfully traverse the Examiner's restriction requirement for the following reasons.

The restriction requirement is improper because it omits "an appropriate explanation" as to the existence of a "serious burden" if a restriction were not required. (MPEP § 803). An examination of all the claims in this application would not pose a serious burden because a search of any one of invention Groups I through IV would require searching the prior art areas appropriate to the other invention Groups.